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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,635	12/12/2005	David Haines	21534-002CIP NATL	9716

30623 7590 02/02/2010

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EXAMINER	
BASQUILL, SEAN M	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
02/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,635	HAINES ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-31 and 34-53* is/are pending in the application.

4a) Of the above claim(s) *17-31,34-47,52 and 53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 48-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *14 May 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Previous Rejections

1. Applicants' arguments, filed 9 October 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

2. Amended Claims 17-31, 34, and newly submitted claims 47, 52, and53 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims require an additional invention, namely diagnosis of ocular inflammation by measurement of a specific biomarker, that is independent and distinct from the process of treating ocular inflammation considered on the merits in the previous office action.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 17-31, 34, 47, 52, and 53 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Similarly, newly submitted Claims 48-51 will be considered as depending from Claim 1, rather than Claim 17, for the purposes of the instant examination.

Status of the Claims

3. Amendments to the Claims, submitted with applicants' response filed 9 October 2009, have been entered. Claims 1, 5, 6, and 17 have been amended, and Claims 16, 32, 33 have been cancelled. New Claims 47-53 have been added. Claims 35-46 remain and 17-31, 34, 47, 52, and 53 are withdrawn as directed to a nonelected invention. Claims 1-15 and 48-51 are presented for examination.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-15 and 48-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*,

86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 47 includes broad recitations of a variety of potential composition components, for example Vitamins A, B6, B12, C, D, and E, Thiamin, Niacin, folate, and so on while also reciting specific compounds which provide the claimed nutrients; these are the narrower statements of the limitation.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4, 8-14, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,103,756 ("Gorsek"), in view of Narsing Rao and Guey-Shang Wu, *Free Radical Mediated Photoreceptor Damage in Uveitis*, 19 PROG. RETINAL EYE RES. 41 (2000) ("Rao").

As a threshold matter, the examiner has interpreted instant Claims 1, 47, and all claims dependent therefrom as requiring the administration of at least a carotenoid and polyphenol selected from the list of compounds in the daily dosages provided in these Claims. In essence, the examiner considers the chart provided in these claims the enumeration of a variety of species in a genus in the manner of a *Markush*-type Claim.

Gorsek describes an orally administrable composition for the treatment of ocular disease such as macular degeneration comprising a combination of nutrients which neutralize free radicals that may contribute to ocular disorders. (C.1, L.5-9, L.25-28). While not spelled out, the examiner asserts this results in systemic administration of the composition as claimed. Specifically, the composition includes zeaxanthin, vitamin C, selenium and other trace minerals, bilberry extract, alpha lipoic acid, n-acetyl-cysteine, quercetin, citrus bioflavanoids, lutein extract, and taurine. (C.2, Table 1). Table 1 indicates that beta carotene (2500 IU),

cholecalciferol (400 IU), selenomethionine (200 mcg), quercetin (100mg), N-acetyl cysteine (200mg), and citrus bioflavonoid (250 mg) are to be delivered in concentrations within the ranges as claimed. (C.2, Table 1). Gorsek indicates that the essential nutrients contained in the composition are shown to have a powerful protective effect on the health of the eye to preserve good vision. (C.1, L.43-45).

Gorsek does not specifically describe the actual treatment of either ocular inflammation or macular degeneration.

Rao indicates that ocular inflammation is in part caused by oxygen metabolites, including oxygen free radicals. (Pg. 41-42). Rao indicates that the administration of free radical scavengers and antioxidants may be beneficial in the treatment of ocular inflammation such as uveitis. (Pg. 62).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to have used the composition of Gorsek in the treatment of macular degeneration as well as ocular inflammation as suggested by Rao. One having ordinary skill in the art would have been motivated to do so because of Rao's suggestion that antioxidants may effectively treat ocular inflammation caused in part by free radical damage, and the fact that Gorsek discloses the usefulness of the composition therein described in protecting against the damage caused by free radicals through their neutralization.

Applicants arguments have been fully considered and are deemed unpersuasive, as the examiner has indicated that the doses of the specific carotenoids and polyphenols listed above are in fact disclosed in Gorsek.

6. Claims 1-14 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek as modified by Rao as applied to Claims 1-4, 8-14, and 51 above, and further in view of U.S. Patent Application Publication 2002/0095000 ("Troyer").

Gorsek as modified by Rao, above, describes the treatment of ocular inflammation or macular degeneration using an antioxidant composition, but does not include omega-3 fatty acids such as DHA or omega 3-fatty acids in the composition.

Troyer describes a composition containing blackcurrant seed oil, a source of both omega-3 and omega-6 fatty acids, as well as cod liver oil, a source of the omega-3 fatty acid DHA, for the promotion of ocular health and treatment of dry-eye syndrome.

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have combined the omega-3 and omega-6 fatty acid composition of Troyer with the composition of Gorsek as modified by Rao to arrive at the composition used in the methods of the instant claims. One of ordinary skill in the art would have been motivated to do so because both compositions are directed to the treatment of ocular diseases and the promotion of ocular health, and it is prima facie obvious to combine two elements known by the art as useful for the same purpose to achieve a third element for achieving the exact same purpose. MPEP § 2144.06.

Applicants arguments have been fully considered and are deemed unpersuasive, as the examiner has indicated that the doses of the specific carotenoids and polyphenols listed above are in fact disclosed in Gorsek.

7. Claims 1-4, 8-15, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek as modified by Rao as applied to Claims 1-4, 8-14, and 51 above, and further in view of U.S. Patent 6,365,622 ("Cavazza").

Gorsek as modified by Rao, above, describes the treatment of ocular inflammation or macular degeneration using an antioxidant composition, but does not include L-carnitine in the composition.

Cavazza teaches that L-carnitine is a powerful antioxidant suitable for oral or topical administration in the treatment of diseases brought about by free radicals. (C.1, L.6-8; L.19-28).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have combined the L-carnitine of Cavazza with the composition of Gorsek as modified by Rao to arrive at the methods of the instant claims. One of ordinary skill in the art would have been motivated to do so because both compositions are directed to the treatment of ocular diseases and the promotion of ocular health, and it is prima facie obvious to combine two elements known by the art as useful for the same purpose to achieve a third element for achieving the exact same purpose. MPEP § 2144.06.

Applicants arguments have been fully considered and are deemed unpersuasive, as the examiner has indicated that the doses of the specific carotenoids and polyphenols listed above are in fact disclosed in Gorsek.

8. Claims 1-4, 8-14, and 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsek as modified by Rao as applied to Claims 1-4, 8-14, and 51 above, and further in view of C. Leigh Broadhurst, *et al*, *Insulin-like Biological Activity of Culinary and Medicinal*

Plant Aqueous Extracts in Vitro, 48 J. AGRIC. FOOD CHEM. 849 (2 March 2000) (hereinafter "Broadhurst"), and Judy McBride, *Cinnamon Extracts Boost Insulin Sensitivity*, AGRIC. RES. 21 (July 2000) (hereinafter "McBride").

Gorsek as modified by Rao, above, describes the treatment of ocular inflammation or macular degeneration using an antioxidant composition, but does not indicate that cinnamon bark powder containing methyl hydroxy chalcone polymer should be included in the composition.

Broadhurst indicates that cinnamon, in the form of powder ground from bark (Pg. 849), contain high levels of chalcone polymers which, in the context of Broadhurst's investigation, were found to demonstrate significant insulin-like or insulin potentiating activity. (Pg. 850). While Broadhurst makes no mention of the chalcone polymers antioxidant activity, McBride indicates that Methyl Hydroxy Chalcone Polymer prevents the formation of oxygen radicals, and may be sued as an antioxidant supplement. (Pg. 21).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have combined the cinnamon bark powder of Broadhurst with the composition of Gorsek as modified by Rao to arrive at the methods of the instant claims. One of ordinary skill in the art would have been motivated to do so because the composition of Gorsek as modified by Rao directed to the treatment of ocular diseases and the promotion of ocular health using antioxidant compositions, and Broadhurst and McBride indicate that cinnamon bark powders contain powerful antioxidants shown to prevent the formation of oxygen free radicals. It is *prima facie* obvious to combine two elements known by the art as useful for the same purpose to achieve a third element for achieving the exact same purpose. MPEP § 2144.06.

Conclusion

No Claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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